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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/460,605

Applicant(s)

Disher

Examiner
Gollamudi S. Kishore, Ph.D

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1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 4, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, and 13-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, and 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

The request for the extension of time and amendment filed on 10-4-01 are acknowledged.

Claims included in the prosecution are 1-8, 10 and 13-25.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 15-16 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

- 3. Claims 21-24 provide for the use of the polymersomes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.**

Claims 15-16 and 21-24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim

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under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Applicant did not address this issue (previously made on claims 15 and 16) and hence the rejection is maintained.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-4, 10, 13-15 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Henselwood (Macromolecules, 1998) or Hajduk (J. Of Phys. Chem.,

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1998) or Ding (J. Phys. Chem., 1998) or Cornelissen (1998) or Fendler (Science, 1984) all are of record.

The above references teach polymeric vesicles having a membrane; the polymers are diblock polymers (note abstracts in each). The references meet the requirements of instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant in general argues that the definitions for the terms have been given in the specification on pages 13 and 14. This argument is not persuasive since the claims are given the broadest reasonable interpretation and in instant case the cited references read on instant claims. If applicant's intend is to claim specific composition, then the critical features defining applicant's composition and differentiating from the prior art should have been recited.

Applicant in particular argue that instant claim recites vesicles and none of the references recite vesicle. Applicant is incorrect. Henselwood on page 4215, column 2 refers to his composition as micelles. As is known in the art, micelles have a single membrane layer and are vesicles. Applicant's own definition indicates that vesicles are essentially semi-permeable bags (see page 9 of applicant's response). Similar is the case with Hajduk who discusses the lamellarity and amphiphilic nature of the polymers and refers to it as micellar (note page 4271, col. 2, and page 4273, col. 2). Ding clearly teaches vesicular preparation on page 6108, col. 2, line 5 et seq. Fendler similarly refers to his preparation as

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‘polymerized surfactant vesicles’ (see the title itself). Cornelissen teaches clearly the formation of vesicles by the polymers (note the summary on page1427). Instant claims read on the references and the rejections are maintained.

- 6. Claims 1-4, 6, 10, 13-18 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Hentze (Macromolecules, 1999) of record.**

Hentze teaches polymeric vesicles having a membrane; the polymers are diblock polymers (note abstract). The reference meets the requirements of instant claims.

Applicant’s arguments are similar to those advanced for the above rejections and hence the same response is applicable. Hentze clearly teaches lamellar structures (note figures 4 and 5). Applicant’s arguments based on page 14 of instant specification are not persuasive and this point has been addressed above.

- 7. Claims 1-2, 7-8, 14-18 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu (Macromolecules, 1999) of record.**

Liu teaches polymeric vesicles having a membrane, acryloylphospholipids which are cross-linked (note abstract). The reference meets the requirements of instant claims.

Applicant’s arguments arguments have been fully considered, but are not found to be persuasive. Applicant is incorrect in stating tha Liu fails to disclose vesicles. Liu on page 5520 clearly teaches vesicles.

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Claim Rejections - 35 U.S.C. § 103

8. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 3-8, 10 and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding, Henselwood, Fendler or Hentze cited above.**

The references of Ding, Henselwood, Fendler and Hentze are all suggestive of the potential applications of the polymeric vesicles for the drug delivery. The use of the polymeric systems taught by Ding, Henselwood, Fendler or Hentze for drug delivery would have been obvious to one of ordinary skill in the art since these references are suggestive of the drug delivery. The criticality of a triblock polymer is not readily apparent to the examiner since from the references it would appear that the amphophilic nature of the polymer is the determinant factor.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on presumed lack of teachings of vesicles in the prior art. These arguments have been addressed above. As to applicant's arguments that none of the references teaches the use of the vesicles for drug delivery, the examiner points out that all of the references cited clearly teach the application of these

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polymers for drug delivery (note the Introuduction section in Henselwood and the conclusion sections in others).

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

December 20, 2001